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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Facility ID#209593
Central File # 1939598

February 7, 1997

Mr. Richard W. Waller, Administrator
Southeast Nebraska Mobile Diagnostic Services, Inc.
245 South 84th Street, Suite 100
Lincoln, Nebraska 68516

Dear Mr. Waller,

Your Number 4 mobile mammography system was inspected on December 13, 1997, by a representative of the State of Nebraska, acting on behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 900.12, as follows:

> 21 CFR Part 900.12(d)(2): The number of masses scored in the phantom image was 1.5 and did not meet the required number. The minimum number required for masses is 3 (Lorad Medical Systems, Inc. Transpo 350; Mobile.)

The specific deficiency noted above appeared under the level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your mobile facility.

In addition, Level 2 noncompliances were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

> 21 CFR Part 900.12(d)(2): The number of speck groups scored in the phantom image was 2.0 and did not meet the required number. The minimum number required for speck groups is 3.

> 21 CFR Part 900.12(d)(1)(i): The processor was deviating significatly from expected performance measures (measured 96 for extended processing--Fuji RGII.)

21 CFR Part 900.12(d)(4): No medical audit system to track positive mammograms was in place.

21 CFR 900.12(a)(1)(iv)(A): The interpreting physician did not meet the continuing experience requirement, i.e., interpreting an average of 40 patient examinations per month over a 24 month period following the date of the completion of the initial requirement: [redacted] M.D.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- **impose civil money penalties** on a facility of up to $10,000 **for each failure** to substantially comply with, **or each day** of failure to substantially comply with, the Standards.
- **suspend or revoke a facility's FDA certificate** for failure to comply with the Standards.
- **seek an injunction in federal court** to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to **correct all** of the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records **(Note: Patient names or identification should be deleted from any copies submitted).**

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to B. Belinda Collins, Regional Radiological Health Representative, Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. Collins at 214-655-8100, extension 148.

Sincerely yours,

Edward R. Esparza
Regional Food and Drug Director

cc: Julia Schmitt, Program Manager
Nebraska Health and Human Services
Department of Regulation and Licensure
301 Centennial Mall South
Post Office Box 95007
Lincoln, NE 68509-5007

cc: HFA-224
HFC-230
HFC-240
HFI-35 (redacted copy for public display)
HFZ-240 ATTENTION: Denise Robinson, DMQRP
HFZ-322
HFR-SW19 (RRHR)